

**DOCKET NO. HARR0032-101**

**PATENT**

**APPLICATION SERIAL NO. 10/607,479**

**SUPPLEMENTAL AMENDMENT AND REQUEST FOR RECONSIDERATION**

**DATED AUGUST 22, 2006**

**REPLY TO FINAL REJECTION OF FEBRUARY 22, 2006**

**REMARKS**

Claims 2 and 4-31 were pending. Claims 4, 23-25, and 29-31 are canceled herein. All pending claims were rejected in the Final Rejection.

An amendment was filed in response to the Final Rejection on June 28, 2006. An Advisory Action followed, advising that the amendment was not entered because two of the claims depended upon canceled claims and no terminal disclaimer had been submitted to address the outstanding obviousness-type double patenting rejection. Additionally, a new rejection for statutory double patenting was raised allegedly in view of the amendments. Following a telephonic interview, conducted on July 21, 2006, to discuss the statutory double-patenting rejection, the Office forwarded an Interview Summary, dated as mailed July 25, 2006, in which the statutory double patenting rejection was discussed. The substance of that interview follows.

Pursuant to MPEP 713.04, Applicants herein summarize the substance of the interview. Pursuant to the "Summary of Record of Interview Requirements," Applicants refer to the identification of the claims discussed. During the telephonic interview conducted on July 21, 2006, Applicants' reminded the Examiner that a discussion of whether or not the amendments proposed would render the claims identical in scope to the claims of U.S. Patent No. 6,60,037 had occurred during the telephonic interview conducted on May 30, 2006. Since the Examiner had concluded, during that interview, that the claims would not be identical in scope, noting the requirement in the claims of the issued patent that the expressible gene be useful for the treatment of cancer, and did not himself raise the issue in the Interview Summary dated as mailed June 5, 2006, Applicants did not consider it to be an issue and did not themselves raise it in their summary submitted with their response. Applicants were quite surprised, then, to see the issue raised in the Advisory Action and promptly called the Examiner requesting a discussion of the same. As indicated in the Interview Summary dated as mailed July 25, 2006, the Examiner has, upon further consideration, deemed that the proposed claims would not be identical in scope because there is no evidence of record, nor indeed that he could think of, that all species of the types of genes listed would be useful for treating

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cancer. As discussed below, during the telephonic interview conducted on May 30, 2006, the Examiner had noted a utility for such genes other than treatment of cancer. Regardless, in the Interview Summary dated as mailed July 25, 2006, the Examiner concluded that the double-patenting was of the obviousness-type only, not statutory.

As the interview was telephonic, no exhibit was shown, nor was any demonstration conducted.

Because the previous amendment was not entered, Applicants repeat the substance of the amendment herein, making the additional amendments as required in the Advisory Action, and include herewith a terminal disclaimer over U.S. Patent No. 6,608,037. In view of the foregoing amendments and arguments below, Applicants respectfully request withdrawal of all rejections upon reconsideration.

**Substance of the Interview Conducted on May 30, 2006**

Again, Applicants wish to thank the Examiner for the helpful interview conducted on May 30, 2006. Pursuant to MPEP 713.04, Applicants herein summarize the substance of the interview. Pursuant to the "Summary of Record of Interview Requirements," Applicants refer to the identification of the claims discussed and the principal proposed amendments discussed in the Interview Summary Form completed by the Examiner, but add that all pending claims were discussed in general terms, and that, specifically, the cancellation of the method of treatment claims and of all the dependent claims reciting the specific types of genes, after these recitations had been added to the independent claims from which they depend.

As the interview was telephonic, no exhibit was shown, nor was any demonstration conducted.

The obviousness-type double patenting rejection over U.S. Patent No. 6,608,037 was also discussed. Applicants advised that a terminal disclaimer will be filed upon an indication that the claims are otherwise allowable.

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Applicants arguments focused upon the outstanding rejection for alleged lack of enablement. Applicants noted that this rejection focused upon how one identifies what elements should be included in the construct, i.e., which expressible gene, when all that is specified is that the disease is characterized by the presence of TCF/β-catenin heterodimers. Applicants suggested amending the independent claims to recite the specific types of genes to be included in the construct, and removing the language regarding the characterization of the disease. Applicants maintained, however, that the identification of diseases characterized by the presence of TCF/β-catenin heterodimers is enabled by the specification as filed, even though the diseases themselves, other than cancer, are not specifically disclosed, because Applicants disclose a method for identifying diseases so characterized using reporter genes and diseased cells. The utility of the inventions of such claims was acknowledged during the interview including, for example, to remove cancerous cells from tissue for subsequent use.

The Examiner indicated during the interview that making the amendments discussed above would overcome the outstanding enablement rejection.

Amending the claims to remove dependencies upon canceled claims was also discussed. These amendments would overcome the outstanding rejection for indefiniteness.

#### **Rejections under 35 U.S.C. § 112, first paragraph**

Claims 2 and 4-31 were rejected in the Final Rejection under 35 U.S.C. § 112, first paragraph, as allegedly nonenabled. Consistent with the discussion during the interview, claims 2, 9, 12, and 15 have been amended to recite the specific types of genes, and to eliminate the recitation regarding characterization of the disease. Accordingly, claims 4, 29, 30, and 31, have been canceled. Additionally, the method of treatment claims, claims 23-25, have also been canceled.

Applicants respectfully request that this rejection be withdrawn.

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**Rejections under 35 U.S.C. § 112, second paragraph**

Claims 4-8, and 20-28 were rejected under 35 U.S.C. §112, second paragraph, as allegedly indefinite for depending upon canceled claims. Specifically, the Office noted that claims 4, 7, 20, 21, 23, and 26 recited claims that had been canceled, with the remaining rejected claims being dependent on one of these former claims. Claims 7, 20, 21, and 26 have been amended to no longer depend upon canceled claims. Claims 4 and 23 have been canceled.

Applicants respectfully request that this rejection be withdrawn.

**Rejection for obviousness-type double patenting**

A terminal disclaimer is enclosed.

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### CONCLUSION

Applicants respectfully submit that the current application is in condition for allowance and request early notification of the same.

Respectfully submitted,

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